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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/579,121

03/12/2007

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WSP243US

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7590

05/25/2010

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EXAMINER

MACAULEY, SHERIDAN R

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

05/25/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/579,121	<b>Applicant(s)</b> BLUME ET AL.	
	<b>Examiner</b> SHERIDAN R. MACAULEY	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6-8,11-14,16-18 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-8,11-14,16-18 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A response and amendment were received and entered on February 25, 2010. All evidence and arguments have been fully considered. Claims 2-5, 9-10, 15, 19 and 20 are cancelled. New claims 24-28 have been added. Claims 1, 6-8, 11-14, 16-18 and 21-28 are pending.

### ***Election/Restrictions***

1. Applicant's addition of an additional method, i.e., the method recited in claim 28, to the pending claims is noted. Since applicant elected the product groups (claim 1 and its dependents) for examination in the response filed on July 29, 2009, this method claim has been withdrawn from further consideration, there being no allowable generic or linking claim.
2. In the reply filed on February 25, 2010, applicant argues that the requirement for restriction should be withdrawn because all claims now recite a special technical feature that makes a contribution over the prior art. Applicant further argues that the species election requirement made in this application is improper because the independent claim recites a special technical feature, thereby rendering the species election requirement improper. This is not found persuasive because the technical feature that is common to the groups is a composition having a carrier system comprising membrane-forming lipids, a microcirculation-promoting substance (specifically, caffeine), an anticoagulant and a vasoprotective agent. However, it would have been obvious at the time of the invention for one of ordinary skill in the art to prepare a composition

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comprising these features, as discussed in detail below. Briefly, the technical feature that is common to the groups is rendered obvious by Cho et al. (US 5,667,793) in view of Bombardelli et al. (US 5,679,358), or by Mantelle et al. (US 6,562,363) and Hosokawa et al. (US 2003/0035826 A1). Therefore, there is no special technical feature that is common to the groups or species of the invention that makes a contribution over the prior art. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 27 and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions and species, there being no allowable generic or linking claim.

4. Claims 1, 6-8, 11-14, 16-18 and 21-26 are examined on the merits in this office action.

### ***Claim Rejections - 35 USC § 102***

5. Rejections under 35 USC 102 are withdrawn due to amendment.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 6-8, 11-14, 16-18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US 5,667,793; cited in previous action) in view of Bombardelli et al. (US 5,679,358; cited in previous action). The claims recite a combined cosmetic or therapeutic composition having a carrier system comprising membrane forming lipids and having a triple combination of active ingredients, wherein (a) at least one active ingredient is selected from anticoagulants, (b) at least one ingredient is selected from vasoprotective agents, specifically aescin, and (c) at least one active ingredient is a vasodilatory microcirculation promoting substance, specifically caffeine. The claims further recite that the carrier system is vesicular and that the membrane-forming lipids include phospholipids, ceramides and diacylglycosides. The claims further recite that the vasoprotective agent is in an amount of 4-6% by weight aescin, and the microcirculation-promoting substance is present at 0.1-2% by weight, specifically 0.5-1.5% caffeine. The claims further recite that the membrane forming lipids contain at least 70% by weight phosphatidylcholine and that the carrier system contains linoleic acid in stabilized form in an amount of 2.5-4.5% by weight. The claims also recite that the preparation further contains at least one thermoreceptor-agonist

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selected from capsaicin in an amount of 0.1-1% by weight and nicotinic acid, nicotinic acid amide, nicotinic acid ester or mixtures thereof in an amount of 0.5-5% by weight.

The claims further recite that the preparation contains 10-25% ethanol. The claims further recite that the anticoagulants are selected from haptans, fucoidans, hirudins, pentapeptides, coumarin derivatives and mixtures thereof.

9. Cho teaches a therapeutic composition for the treatment of cellulite comprising a carrier system comprising membrane-forming lipids (ceramide lipids), a microcirculation-promoting substance (caffeine) and a vasoprotective agent (0.5% escin, i.e., aescin; see Example 5, column 9). The reference teaches that caffeine may be present at 0.5-3% by weight (col. 3, lines 49-59). Cho teaches that the compositions may comprise ethanol at 25% (see Example 7, column 10). Cho teaches that the composition may comprise trilinoleate (a stabilized linoleic acid; col. 5, lines 4-14) and nicotinate (nicotinic acid; col. 4, lines 38-40). Cho does not specifically teach a composition comprising an anticoagulant or phosphatidylcholine, or that the composition comprises linoleic acid, nicotinic acid or aescin in the amounts recited in the claims.

10. Bombardelli teaches compositions for the treatment of cellulite comprising esculoside, which is a coumarin derivative (col. 2, lines 4-49), agents to improve circulation such as caffeine and phosphatidylcholine as a membrane forming lipid (abstract, col. 4-5, Example II).

11. At the time of the invention, a composition comprising nearly all of the claimed components was known in the art, as taught by Cho. It was further known that similar compositions for the same purpose, the treatment of cellulite, could have been

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formulated with esculose and phosphatidylcholine as the membrane-forming lipid, as taught by Bombardelli. One of ordinary skill in the art would have been motivated to combine these teachings with a reasonable expectation of success by using the agents of Bombardelli in the method of Cho because Bombardelli teaches that the esculosides are particularly beneficial in such compositions and Cho teaches that additional beneficial components may be added to the compositions taught therein; further, Cho teaches that any known carrier for similar preparations would have been useful as the carrier in the composition, and Bombardelli teaches that such preparations comprising phosphatidylcholine are favorable. Further, Cho teaches that the emollient, such as the lineolic acid, may be present in amounts between about 5% and 30% (col. 4, lines 64-67, col. 5, lines 4-14). One of ordinary skill in the art would therefore have been motivated to use lineolic acid in the composition at 4.5% in the course of routine optimization of the composition. Also, although the reference does not specifically teach the amount of nicotinic acid or aescin recited in the claims, the additional components taught by the reference that may be included in the compositions are present at amounts within those ranges and one of ordinary skill in the art would have been motivated to add the additional components in amounts within the claimed ranges. It would therefore have been obvious to one of ordinary skill in the art to combine the cited teachings of the prior art to arrive at the claimed invention.

12. Claims 1, 11-14, 16-18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Mantelle et al. (US 6,562,363) and Hosokawa et al. (US

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2003/0035826 A1). The claims recite a combined cosmetic or therapeutic composition having a carrier system comprising membrane forming lipids and having a triple combination of active ingredients, wherein (a) at least one active ingredient is selected from anticoagulants, (b) at least one ingredient is selected from vasoprotective agents, specifically aescin, and (c) at least one active ingredient is a vasodilatory microcirculation promoting substance, specifically caffeine. The claims further recite that the vasoprotective agent is in an amount of 4-6% by weight aescin, and the microcirculation-promoting substance is present at 0.1-2% by weight, specifically 0.5-1.5% caffeine. The claims further recite that the membrane forming lipids contain at least 70% by weight phosphatidylcholine and that the carrier system contains linoleic acid in stabilized form in an amount of 2.5-4.5% by weight. The claims also recite that the preparation further contains at least one thermoreceptor-agonist selected from capsaicin in an amount of 0.1-1% by weight and nicotinic acid, nicotinic acid amide, nicotinic acid ester or mixtures thereof in an amount of 0.5-5% by weight. The claims further recite that the preparation contains 10-25% ethanol. the claims further recite that the anticoagulants are selected from heparins, fucoidans, hirudins, pentapeptides, coumarin derivatives and mixtures thereof. The claims further recite that the anticoagulant contains the anticoagulant in an amount of 0.1-10% by weight, specifically fucoidan in an amount of 1.0-3.0% by weight.

13. Mantelle teaches compositions for topical administration of active agents comprising a fucoidan as a bioadhesive (abstract, col. 5, line 41-col. 6, line 4). The reference teaches that the compositions may further comprise caffeine (col. 25, lines 2-



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15), lecithin (membrane-forming lipids; col. 27, lines 4-6), aescin (escin; col. 29, lines 46-49) as a vasoprotective, an anticoagulant such as heparin (col. 29, line 57) and an agent such as nicotine (col. 17, lines 20-22).

14. Hosokawa teaches compositions for topical administration of active agents, said compositions comprising extracts such as *Fucus vesiculosus* (bladderwrack, which comprises fucoidan; p. 3, par. 34, and used at 1% by weight at p. 5, par. 61), *Aesculus hippocastanum* (horse chestnut, which comprises aescin; p. 3, par. 34) and caffeine (p. 5, par. 61). The reference further teaches compositions comprising ethanol (10% by weight, p. 5, par. 61).

15. Although neither of the references specifically teaches the claimed composition, each reference teaches that the compositions of the instant claims comprises ingredients that were well known at the time of the invention to be useful in compositions for the topical administration of agents and that it was known at the time of the invention to combine such agents into compositions for treatment of various conditions. One of ordinary skill in the art would therefore have recognized that the combination of the claims would have been motivated to combine the claimed components in a composition in the course of routine experimentation, particularly for the preparation of a composition for the topical administration of agents. Although the references do not specifically teach the amounts of some of the components recited in the claims, the additional components taught by the references that may be included in the compositions are present at amounts within those ranges and one of ordinary skill in the art would have been motivated to add the additional components in amounts within

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the claimed ranges. Further, one of ordinary skill in the art would have been had a reasonable expectation of success in combining the ingredients as claimed because the references teach that the components are suitable for combination with a wide range of ingredients. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of the prior art to arrive at the claimed invention.

16. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Arguments***

17. Applicant's arguments filed February 25, 2010 have been fully considered but they are not persuasive. Applicant argues that neither Cho nor Bombardelli teach an anticoagulant in the composition. However, the compositions of Bombardelli comprise esculoside, which is a coumarin derivative. The instant disclosure teaches that coumarin derivatives may be added as anticoagulant components of the composition. It would have been obvious to combine the teachings of Cho and Bombardelli to arrive at the claimed invention for the reasons set forth above. Although Bombardelli does not specifically teach that the esculoside is an anticoagulant, the reference teaches that the compound may be used to improve blood flow and there is no evidence that the compound is not an anticoagulant. In the absence of such evidence, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences

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would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

18. Although applicant further argues that the claimed invention produces surprisingly optimal results, this evidence is not commensurate in scope with the claims. Applicant specifically states that the advantages are illustrated to provide improved effects over prior art preparations in figure 1; however, it does not appear that this comparison is demonstrated in the figure, which appears to depict that only one composition is tested. In examples 1 and 2, a composition is tested that is not commensurate in scope with the broadly drawn claims in the instant application; however, it is also unclear whether the invention that is tested in these examples provides any unexpected advantage.

19. In response to applicant's argument that the claimed invention provides an agent for treatment of hematomas whereas the prior art is drawn to an agent for treatment of cellulitis, it is noted, that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

20. Therefore, applicant's arguments have been fully considered, but they have not been found to be persuasive.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A. Davis/  
Primary Examiner, Art Unit 1651